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DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration

[Docket No. 02N–0259]

Agency Information Collection Activities; Proposed Collection; Comment Request; Telephone Questionnaire Administration to Control Subjects Recruited into FDA Lyme Vaccine Safety Study, "A Case-Control Study of HLA Type and T-Cell Reactivity to Recombinant Outer Surface Protein A and Human Leukocyte Function-Associated Antigen-1"

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the use of a survey questionnaire to be administered by telephone interview to control subjects recruited into and participating in a vaccine safety study conducted by FDA to investigate reports of arthritis following administration of the Lyme disease vaccine. Informed consent for administration of this questionnaire will have been received prior to the interview, and the interview is to be conducted at a time specified by the control subject at the time of initial recruitment into this study. This questionnaire is an abridged version of one used in followup survey interviews with persons reported to the

national Vaccine Adverse Event Reporting System (VAERS) as having developed joint problems or arthropathy following Lyme disease vaccine administration.

DATES: Submit written or electronic comments on the collection of information by [*insert date 60 days after date of publication in the* **Federal Register**].

ADDRESSES: Submit electronic comments on the collection of information to http://www.accessdata.fda.gov/scripts/oc/dockets/edockethome.cfm. Submit written comments on the collection of information to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Jonna Capezzuto, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4659.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Telephone Questionnaire Administration to Control Subjects Recruited into FDA Lyme Vaccine Safety Study, "A Case-Control Study of HLA Type and T-Cell Reactivity to Recombinant Outer Surface Protein A and Human Leukocyte Function-Associated Antigen-1"

Section 505 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355), requires that important safety information relating to all human prescription drug products be made available to FDA so that it can take appropriate action to protect the public health when necessary. Section 702 of the act (21 U.S.C. 372) authorizes investigational powers to FDA for enforcement of the act.

Under section 519 of the act (U.S.C. 360i), FDA is authorized to require manufacturers to report medical device-related deaths, serious injuries, and malfunctions to FDA and to require user facilities to report device-related deaths directly to FDA and to manufacturers, and to report serious injuries to the manufacturer. Section 522 of the act (21 U.S.C. 360l) authorizes FDA to require manufacturers to conduct postmarket surveillance of medical

devices. Section 705(b) of the act (21 U.S.C. 375(b)) authorizes FDA to collect and disseminate information regarding medical products or cosmetics in situations involving imminent danger to health or gross deception of the consumer. Section 903(d)(2) of the act (21 U.S.C. 393(d)(2)) authorizes the Commissioner of Food and Drugs (the Commissioner) to implement general powers (including conducting research) to carry out effectively the mission of FDA. These sections of the act enable FDA to enhance consumer protection from risks associated with medical products usage that are not foreseen or apparent during the premarket notification and review process.

FDA's regulations governing application for agency approval to market a new drug (21 CFR part 314) and regulations governing biological products (21 CFR part 600) implement these statutory provisions.

Currently FDA monitors medical product related postmarket adverse events via both the mandatory and voluntary MedWatch reporting systems using FDA forms 3500 and 3500A (OMB control number 0910–0291) and the vaccine adverse event reporting system (VAERS) using form VAERS–1. Health care providers and manufacturers are required by law (42 U.S.C. 300aa–25) to report adverse events following vaccination listed in the vaccine injury table. Reports for reactions to other vaccines are voluntary, and are received from vaccine recipients, their health care providers, and other reporters.

FDA is seeking OMB clearance to collect vital information through the use of the proposed survey questionnaire for control subjects participating in this vaccine safety study. The intended respondents are control subjects previously recruited to participate in this study, and are matched with case subjects reported to VAERS who developed arthritis following Lyme vaccine administration. Informed consent for administration of this questionnaire will

have been received prior to the interview, and the interview is to be conducted at a time specified by the control subject at the time of initial recruitment into this study. Case and control subjects should have similar age, gender, and ethnic backgrounds. Specific genetic and immune factors will be compared between case and control subjects. This is a common, accepted type of epidemiological study called a case-control study. Information collected includes medical and vaccination history, family history, and possible exposures such as in the workplace that may play a part in the development of arthritis in some patients. FDA will use the information gathered from the use of this survey questionnaire to ensure appropriate matching of cases and controls in the study and to assess possible factors which may factor in the development of this adverse event. This study was approved by the FDA Research Involving Human Subjects Committee on February 15, 2002 (RIHSC #01–028B). This survey questionnaire is an abbreviated version of one used during enhanced surveillance followup of adverse events following Lyme vaccine administration reported to VAERS. The use of the vital information gathered using this survey questionnaire will aid FDA in assessing risks that may be associated with vaccine product usage that are not foreseen or apparent during the premarket notification and review process, so the agency may take appropriate public health or regulatory action including dissemination of this information as necessary and appropriate.

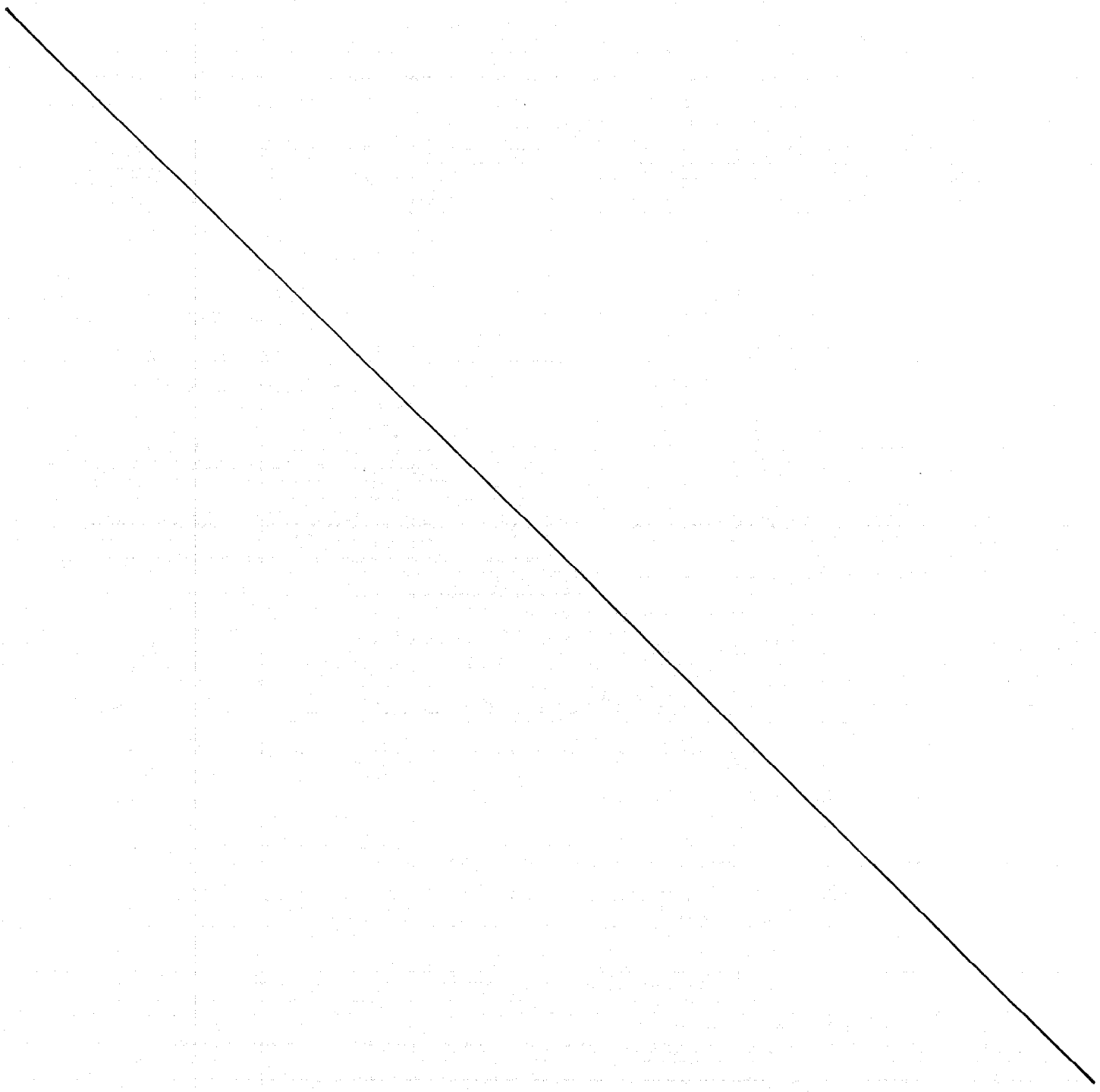
FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

Survey	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
"A Case-Control Study of HLA Type and T-Cell Reactivity to Recombinant Outer Surface Protein A and Human Leukocyte Function-Associated Antigen-1"	225	1	225	0.5	112.5

[1]There are no capital costs or operating and maintenance costs associated with this collection of information.

FDA projects that there will be up to 75 case subjects recruited into this study with 3 control subjects recruited for each case subject, with a total maximum of 225 survey questionnaire respondents. FDA also projects a response time no greater than 0.5 hours per response. This estimate is based on previous results experienced with the instrument during enhanced surveillance followup of adverse events reported to VAERS. Respondents will



only be contacted once during conduct of this study for the purposes of collection of vital information using this survey questionnaire.

Dated: 6-21-02

June 21, 2002.

Margaret M. Dotzel,
Associate Commissioner for Policy.

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